



## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Department (Board) of Juvenile Justice
<b>Virginia Administrative Code (VAC) citation</b>	6VAC35-170
<b>Regulation title</b>	MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE
<b>Action title</b>	To provide for a comprehensive review of the process for reviewing and approving research proposals involving human subjects, to effectuate the provisions of Chapter 5.1 (Section 32.1-162.16 et seq.) of Title 32.1 for human research.
<b>Date this document prepared</b>	February 14, 2014

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

In compliance with the provisions of Chapter 5 (§ 31.1-162.16 et seq.) of Title 32.1 of the Code of Virginia, the regulation establishes minimum standards for research on human subjects under the care of the Department of Juvenile Justice (Department). It requires that the Department establish a human research review committee, provides criteria for that committee to use in evaluating proposals involving human research, provides for informed consent by human subjects or their authorized representatives, establishes minimum requirements for researchers, and requires annual reports to the Governor, the General Assembly, and the Board of Juvenile Justice (Board) on human research projects. The regulation also establishes a process for reviewing and approving research on records and data of the Department when human research is not involved. Section 66-10.1 of the Code of Virginia directs the Board to promulgate regulations pursuant to the Administrative Process Act to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research to be conducted or authorized by the Department.

This regulation was last reviewed and amended on February 9, 2005.

## Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.*

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Section 66-10.1 of the Code of Virginia directs the Board to promulgate regulations pursuant to the Administrative Process Act to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research to be conducted or authorized by the Department. Thus, the regulation is mandatory.

The Board is empowered with general authority to promulgate regulations by § 66-10 of the Code of Virginia that states the Board may "promulgate such regulations as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by the Director or the Department."

## Need

*Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.*

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The regulation applies to all juveniles under the care of the Department or in facilities regulated by the Board of Juvenile Justice. The focus of the regulation is to maintain the standards and practices for research on human subjects under the Department's care so as to protect the safety, rights, and confidentiality of human subjects.

Revisions are needed to update certain regulatory provisions to reflect administrative changes appropriately and promote best practices.

## Substance

*Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.*

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The regulation will be reviewed and modified to ensure that it supports the goals of the Department to provide effective use of human research.

The Department, through an advisory committee, anticipates the following changes:

- Clarify the definition of "Minimal risk" to mirror the federal definition for prisoners.
- Clarify the scope of the exemptions provided for in section 90.
- Expand and clarify the requirements for proposals for external research provided for in section 100, including specific provisions for protecting confidentiality.
- Require annual progress reports when the research is not completed within one year of approval.
- Clarify requirements for research proposals not involving human research including aggregate data requests and collaborative research.

- Clarify conflict of interest provision when a member of the committee is seeking to conduct research by incorporating and abstention provision.
- Strengthen the informed consent requirements provided for in section 160.
- Clarify the requirements for reports of the findings of the study.

## Alternatives

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

As part of the revision process, the Department assessed whether any of the needed changes, clarifications, or updates can be accomplished through additional guidance documents or training rather than revising the regulatory provisions. The conclusion was reached that reviewing and amending the current regulation is the only practicable alternative for addressing certain issues identified during the review of this regulation and in keeping with the Administrative Process Act.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.*

*Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is \_\_\_\_\_; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to **Barbara Peterson-Wilson, 600 East Main Street, 20th Floor, Richmond, VA 23219, (804) 588-3902, FAX (804) 371-6490, or Barbara.Peterson-Wilson@djj.virginia.gov**. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

The Department does not intend to use a panel to assist in the development of this regulatory proposal. However, if you are interested submitting comments on whether a panel should be utilized in this regulatory review process, please contact Barbara Peterson-Wilson.

**Family impact**

*Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The regulation is not anticipated to have a direct impact, either positively or negatively, on the institution of the family and family stability. The regulation does include provisions for parents to be involved in giving informed consent to human research involving a juvenile. As such, it maintains parental authority and rights in determining whether their children participate in human research. The regulation neither encourages or discourages economic self-sufficiency, self-pride, and the assumption of responsibility. The regulation does not strengthen or erode marital commitment or increase or decrease disposable family income.

**Periodic review and small business impact review report of findings**

*If this NOIRA is the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

*In addition, please include, pursuant to Code of Virginia § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.*

As required by statute and Executive Order, this regulation was subject to and submitted for periodic review. A public comment period was held through July 8, 2011. Comments received were:

<b>Commenter</b>	<b>Comment</b>	<b>Agency response</b>
Heber, M. Student Services	I hope it brings better results. Let's see if all this concludes and gives some results or it just remains a useless discussion on this.	Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.
May Anderson	Keep up the great work! I am sure results will follow soon.	Thank you for your comments
Cameron Fenley	I object. I object the decision for reviewing this regulation as the existing one already provides lots of beneficial things like the existing redulation requires a review committee, deal room, consent from human subjects, annual reports to the Governor and many other things. This regulation should not be changed.	Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.

Todd Owen	Very interesting. Again, will the results be best for the citizens? Let's hope our elected officials are thinking about the citizens!	Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.
Kelly J	RE. Where can I uncover more information about this please?	Thank you for your comments. Information related to the stages of the administrative process can be found on the Virginia Regulatory Town Hall website <a href="http://townhall.virginia.gov">http://townhall.virginia.gov</a> . Regulations related to the human subject research can be located in Title 6, Agency 35, Chapter 170 in the <i>Virginia Administrative Code</i> .
Sarah Levins	Info. I agree with Kelly. More information is needed for citizens of Virginia to review before this should go through. Can anyone point me to a resource where it is detailed better?	Thank you for your comments. Information related to the stages of the administrative process can be found on the Virginia Regulatory Town Hall website <a href="http://townhall.virginia.gov">http://townhall.virginia.gov</a> . Regulations related to the human subject research can be located in Title 6, Agency 35, Chapter 170 in the <i>Virginia Administrative Code</i> .
Merrill	No objection. I totally disagreed with Fenley its really needed to review human research projects.	Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.
Frederik Friis	Interesting with this regulation. I think this is important regulation and I interested with the regulation. Good regulation and good people. Thanks.	Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.

The Department convened a multi-disciplinary committee to review the regulations, which determined that a comprehensive review of and substantive changes to the regulation are necessary to ensure each provision is appropriate, effective, and clear in intent and effect. The proposed changes will result in a regulation that is more clearly written and easily understandable.

Any changes to the regulation should not have any positive or negative impact on small businesses. The regulation meets the criteria set out in the applicable Executive Order in that it is necessary for the protection of public health, safety, and welfare and is clearly written and easily understandable. However, a comprehensive review of the regulation will improve the clarity and understandability.

The regulation continues to be necessary to ensure the safety of individuals subject to human research in programs and facilities regulated by the Board of Juvenile Justice. The regulation is not conflict with state or federal law or regulation. The regulation operationalizes the requirements of federal law and regulation as required by the Code of Virginia.

The regulation was last reviewed and amended on February 9, 2005. Technology, economic conditions, or other factors have changed in the area affected by the regulation in that the Commonwealth continues to advance in paperless technology and the regulations will be reviewed to avoid administrative burdens in the review and approval process for human research.

**Periodic review/small business impact review announcement**

***If this NOIRA will not be used to announce the periodic review/small business impact review of the regulation, please delete this entire section.***

In addition, the agency is undergoing a periodic/small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

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The regulation was last reviewed in 2005. Some of the provisions would best serve the interests of the regulated entities and protected populations by being reviewed, amended, revised, or clarified. Public comment was sought at the periodic review stage. Additionally, public comment will be sought on all provisions and proposed changes at all the stages of the regulatory process.